Registration Decision RD2011-08

Liquid Carbon Dioxide: Cryonite

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Registration Decision for Cyronite

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Carbon Dioxide Technical and Cryonite, containing the technical grade active ingredient liquid carbon dioxide, to control flour beetles, cockroaches and bedbugs.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2010-06, *Liquid Carbon Dioxide: Cryonite*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for liquid carbon dioxide and summarizes the Agency's decision, and the reasons for it. The PMRA received no comments on PRD2010-06. This decision is consistent with the proposed registration decision stated in PRD2010-06.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2010-06, *Liquid Carbon Dioxide: Cryonite* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticide and Pest Management portion of Health Canada's Web site at healthcanada.gc.ca/pmra.

What Is Cryonite?

The Cryonite system consists of a device and liquid carbon dioxide (CO_2). The device releases liquid carbon dioxide as very cold dry-ice particles (referred to as "snow") which, when applied directly to infested sites, rapidly freeze flour beetles, cockroaches and bed bugs. This rapid freezing kills the target insect on contact.

Health Considerations

Can Approved Uses of Cryonite Affect Human Health?

Cryonite is unlikely to affect your health when used according to label directions.

The technical grade active ingredient contained in Cryonite, liquid carbon dioxide, is maintained at extremely low temperature and high pressure. Aside from severe burns and frostbite occurring on contact, the overall toxicity of carbon dioxide in its liquid form could not be determined. As a solid (dry ice), carbon dioxide's effects due to exposure mirror those of the liquid form. The carbon dioxide snow sublimates into the gaseous form of carbon dioxide at room temperature. As a gas, carbon dioxide can affect the cardiovascular, respiratory and neurological systems.

The health risks associated with the use of Cryonite have been assessed and are acceptable. There is a concern with users and bystanders coming into direct contact with the carbon dioxide snow or entering an area where the levels of carbon dioxide gas could exceed safe levels. Accordingly, appropriate handling and use of Cryonite must be observed and precautionary label statements must be followed. When the levels of carbon dioxide gas exceed 5000 ppm, persons without proper respiratory protection should not be permitted to enter the area being treated.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Cryonite is not for use on food or feed, thus dietary risks from food and water are not of concern.

Occupational Risks from Handling Cryonite

Occupational risks are not of concern when Cryonite is used according to label directions, which include protective measures.

Applicators applying Cryonite and other personnel entering a treatment site can come in contact with carbon dioxide as a solid or a gas. Therefore, the label specifies the proper use of Cryonite and provides safety measures to be followed by applicators and personnel entering a treatment site to ensure a negligible risk due to exposure.

Bystander Exposure and Risk

For bystanders and pets, exposure is expected to be negligible if the label instructions and precautionary statements are followed.

Environmental Considerations

What Happens When Liquid Carbon Dioxide Is Introduced into the Environment?

Carbon dioxide is a substance that is naturally occurring in the environment. It is necessary in the respiratory cycle of humans and animals, and required by plants for photosynthesis. The use of liquid carbon dioxide and Cryonite is not expected to cause any adverse environmental effects to non-target organisms.

Under ambient conditions, carbon dioxide is found in a stable gaseous state. Under high pressure and extremely low temperature, it can convert to liquid or solid state, which sublimes into the gaseous state when submitted to lower pressure and higher ambient temperature.

Once the liquid carbon dioxide is released from the Cryonite device as solid snow, it sublimes to gaseous carbon dioxide and disperses in the air. The use of Cryonite is not expected to significantly increase the occurrence of carbon dioxide in the atmosphere.

Value Considerations

What Is the Value of Cryonite?

The value of Cryonite was assessed and it was determined that Cryonite kills flour beetles, cockroaches and bed bugs in structures, furniture, machinery and electrical equipment by rapidly freezing the target insect on contact when applied according to the directions for use. Cryonite can be used in areas where some conventional pest control products cannot be used, such as mattresses, and is compatible with current pest management practices including sanitation (for example, vacuuming) and other pest control products (for example, diatomaceous earth).

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Cryonite to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

There is a concern for users and bystanders coming into direct contact with solid carbon dioxide or entering an area where the levels of carbon dioxide gas could exceed safe levels. Accordingly, appropriate handling and use of Cryonite must be observed and precautionary label statements followed. When the levels of carbon dioxide gas exceed 5000 ppm, persons without proper respiratory protection should not be permitted to enter the area being treated.

Environment

No additional risk mitigation measures or label statements are required.

Other Information

The relevant test data on which the decision is based (as referenced in this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticide and Pest Management portion of Health Canada's Web site (Requesting a Reconsideration of Decision, healthcanada.gc.ca/pmra) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

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[5] As per subsection 35(1) of the *Pest Control Products Act*.

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number: 1801044
Reference: 1997, Response to Regulatory Directive 93-02 items, Data Numbering Code: 2.1, 2.11.1, 2.11.4, 2.13, 2.14.8, 2.3, 2.4, 2.5, 2.6, 2.8, 2.9 Confidential Business Information

PMRA Document Number: 1801054
Reference: 1997, Product specifications - Praxair QA program document P-15-085 excerpts, Data Numbering Code: 2.12 Confidential Business Information

PMRA Document Number: 1801055
Reference: 1997, Praxair CO_2 production plants supplying the Canadian market, Data Numbering Code: 2.11 Confidential Business Information

PMRA Document Number: 1801062
Reference: 1997, Plant and lab %CO_2 test results, Data Numbering Code: 2.11 Confidential Business Information

PMRA Document Number: 1801071
Reference: 1997, Batch test logs - Production plants, Data Numbering Code: 2.13 Confidential Business Information

PMRA Document Number: 1801073
Reference: 1997, Lab test results - plant no. 580, CO_2 analysis, Data Numbering Code: 2.13 Confidential Business Information

PMRA Document Number: 1801074
Reference: 1997, Analytical Equipment - Technology Center, Instrumentation and methodology for gas analysis, Data Numbering Code: 2.13.1 Confidential Business Information

PMRA Document Number: 1801077
Reference: 1997, Quantitative lab test chromatograms - plant no. 580, Data Numbering Code: 2.13 Confidential Business Information

PMRA Document Number: 1801082
Reference: 1997, Quantitative plant chromatograms - plant no. 712, Data Numbering Code: 2.13 Confidential Business Information

PMRA Document Number: 1801087
Reference: 1997, CO_2 solubility data and graphs, Data Numbering Code: 2.14.8 Confidential Business Information

2.0 Human and Animal Health

PMRA Document Number: 1778074
Reference: Acute studies - EP, Data Numbering Code: 4.6

PMRA Document Number: 1778075
Reference: Short term studies - EP, Data Numbering Code: 4.7

PMRA Document Number: 1778076
Reference: Use description/scenario (application and post application), Data Numbering Code: 5.2

PMRA Document Number: 1786346
Reference: 2005, Cooling different geometries, Data Numbering Code: 5.2

PMRA Document Number: 1786347
Reference: Cryonite video chapters - paper, Data Numbering Code: 5.2

3.0 Value

PMRA Document Number: 1786335
Reference: 2005, Use of the Cryonite system for the control of stored product pests, Data Numbering Code: 10.2.3

PMRA Document Number: 1786336
Reference: 2006, Field trial to assess the efficacy of a combined Cryonite/diatomaceous earth treatment against bed bugs, *Cimex lectularius*, Data Numbering Code: 10.2.3

PMRA Document Number: 1786337
Reference: 2006, Laboratory bioassay to assess the efficacy of the Cryonite system against bed bug adult, nymph and egg stages, Data Numbering Code: 10.2.3

PMRA Document Number: 1786339
Reference: 2006, Laboratory bioassay to assess the efficacy of the Cryonite system against German cockroaches and Indian meal moths, Data Numbering Code: 10.2.3

PMRA Document Number: 1786344
Reference: Combatting pests by freezing, Data Numbering Code: 10.2

PMRA Document Number: 1786346
Reference: 2005, Cooling different geometries, Data Numbering Code: 5.2

B. Additional Information Considered

i) Published Information

1.0 Environment

PMRA Document Number: 1811587
Reference: European Commission, 2008, Final review report for the active substance carbon dioxide, SANCO/2987/08 – rev.1, Data Numbering Code: 12.5.8, 12.5.9

PMRA Document Number: 1811592
Reference: The Health and Safety Executive, 2002, Evaluation on carbon dioxide: Application for approval of 'mouse detection unit", Advisory Committee on Pesticides, York, United Kingdom.

PMRA Document Number: 1811595
Reference: United States Environmental Protection Agency, 1991, Reregistration Eligibility Document (RED) on carbon and carbon dioxide, Data Numbering Code: 12.5.8, 12.5.9

PMRA Document Number: 1811599
Reference: United States Environmental Protection Agency, 1991, R.E.D. fact sheet on carbon, Data Numbering Code: 12.5.8, 12.5.9

PMRA Document Number: 1811602
Reference: European Commission, 2007, Competent authority report on carbon dioxide (CAS no. 124-38-9) for use as insecticide (Product type 18), Rapporteur Member State: France, Data Numbering Code: 12.5.8, 12.5.9

PMRA Document Number: 1811604
Reference: European Commission, 2007, Assessment report the for active substance carbon dioxide (PT 14, rodenticides), Annex I&IA – France, Data Numbering Code: 12.5.8, 12.5.9

2.0 Value

PMRA Document Number: 1796733
Reference: Stored product integrated pest management with extreme temperatures, Data Numbering Code: 10.2.1

PMRA Document Number: 1796736
Reference: Use of extreme temperatures in urban insect pest management, Data Numbering Code: 10.2.1, 10.3.2

PMRA Document Number: 1796744
Reference: 2006, Armed Forces Pest Management Board technical guide no. 44, Bed bugs - importance, biology, and control strategies, Data Numbering Code: 10.2.2

PMRA Document Number: 1810545
Reference: Integrated pest management for cockroaches, University Of Connecticut, Data Numbering Code: 10.2.2

PMRA Document Number: 1810551
Reference: le Patourel GNJ, 1993, Cold-tolerance of the oriental cockroach *Blatta orientalis*, Entomol. Exp. Appl. 68: 257-263, Data Numbering Code: 10.2.2

PMRA Document Number: 1810552
Reference: American cockroach, Handbook of Pest Control, 8th edition, Data Numbering Code: 10.2.2